

## REMARKS

Claims 1, 24, 25, 35, 43, 44, and 48 have been amended. New claims 52-58 have been added. Claims 6, 9, 11-13, 21, 26-34, 40, 41, 47, and 49-51 were cancelled in a previous Response. Claims 1-5, 7, 8, 10, 14-20, 22-25, 35-39, 42-46, 48, and 52-58 are presented for the Examiner's review and consideration. Applicants believe the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

### Amendments to the Specification

No new matter has been added by the amendments to the specification made herein.

Paragraphs [0083] and [0090] were amended only to properly refer to the trademark names mentioned therein and to correct an inadvertent typographical error.

Paragraph [0526] was amended only to correct an inadvertent typographical error.

### Amendments to the Claims

No new matter has been added by the amendments to claims 1, 24, 25, 35, 43, 44, and 48 made herein. These claims were amended only to clarify that the elongated insulation sleeve is controllably positionable over the second member (force transmitting member and/or tubular member). This amendment is supported in the specification as originally filed. *See e.g.* paragraph [0537] with Figures 52 and 53 of the published application wherein it is disclosed that the range of motion of the sleeve **1204** over the force transmitting member **1172** can be limited. Furthermore, this motion is not dependent on motion of the second member.

No new matter has been added by the addition of new claims 52-58 made herein. These claims were added only to clarify that the elongated insulation sleeve of the claimed device can include a channel **1206** for engaging a pin **1208** positioned on the second member **1172** (force transmitting member and/or tubular member), wherein the channel **1206** and the pin **1208** cooperate to control the range of motion of the sleeve **1204** over the second member **1172**. These new claims are supported by the specification as originally filed. *See e.g.* paragraph [0537] and Figures 52-55 of the published application.

Rejections under 35 U.S.C. §103(a)

Claims 1-5, 7, 8, 10, 14-20, 22-24, 35-39, 42, 44-46, and 48 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Winston et al. (U.S. Patent 3,513,848; hereinafter “Winston”) in view of Shikhman et al. (U.S. Patent 5,423,796; hereinafter “Shikhman”). Claims 25 and 43 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Winston et al. (U.S. Patent 3,513,848; hereinafter “Winston”) in view of Meade et al. (U.S. Patent 5,478,351; hereinafter “Meade”).

For reasons set forth below, Applicants respectfully submit that both of these rejections should be withdrawn.

It is noted that the references are described individually only to clarify what each reference teaches and not to argue each reference separately.

Winston

Winston discloses an apparatus and a method for forming sutures using ultrasonic vibrational energy. *See abstract.* The apparatus is illustrated in Figures 3, 3A, and 11. This apparatus includes vibrator means **45a** in the form of a hand held instrument, including an ultrasonic transducer or motor **65a** for effecting the high frequency vibrations of the tool member **55a**. The tool member **55a** has an enlarged portion **57a** terminating in a work surface **56a** and a base **66a** secured to insert portion **67a**. The apparatus further includes support means **46a** that acts as an anvil or clamp, so that overlapping layers of suture thread **39a** and **40a** may be compressed between working surface **56a** and a support surface **49a** provided on the vibratory and support means. *See column 10, lines 3-19.* The support means **46a** can include a pair of legs **74a** and **75a** secured together at their lower end by bands **76a** and provided with finger gripping means in the form of individual lugs **77a** that extend outwardly from the upper end of the legs for engagement by fingers of the surgeon or operator **68a**. *See column 10, line 73 to column 11, line 6.* The legs **74a** and **75a** are spaced in relation to each other and can be contoured to conform to the cylindrical configuration of the ultrasonic transducer housing **70a**. *See column 11, lines 13-15.* The apparatus and method of Winston help to eliminate the loosening of a suture after its formation. *See abstract.*

### Shikhman

Shikhman discloses a method for penetrating body tissue using a trocar adapted to provide a surgeon with an indication when the trocar has penetrated the tissue. *See* abstract and column 2, line 50 to column 3, line 3. The trocar includes an obturator assembly, a cannula assembly, and an electric connection assembly. The obturator assembly includes a housing and an obturator. The obturator includes a shaft extending from the housing and a tip secured to the distal end of the shaft. The tip is adapted to penetrate body tissue and to conduct electricity. *See* abstract and column 2, lines 9-15. The cannula assembly includes a housing and a sleeve. The cannula housing includes a longitudinal bore extending therethrough for coaxially receiving at least a portion of the obturator. The sleeve is operatively associated with the bore and extends outwardly from the housing. *See* column 2, lines 15-20. The electric connection assembly is associated within the obturator housing and provides a conductive path between the conductive portion of the obturator shaft and an outer surface portion of the obturator housing. *See* abstract and column 2, lines 21-25. The trocar also includes means for interrupting the conductive path between distal end of portion of the obturator (conductive portion) and the electric connection means upon penetration of the body tissue. *See* column 2, lines 25-28. In one embodiment this means is an obturator sleeve. The obturator sleeve is fabricated from an electrically insulating material and is concentrically positioned about the obturator shaft to limit exposure of portions of the obturator shaft. *See* column 2, lines 34-37. In operation, illustrated in Figure 12, once obturator tip **20** of obturator shaft **18** completely penetrates the body tissue, the distal end **24a** of obturator sleeve **24** prohibits the tip from further contact with the body tissue to inhibit or break the electrical circuit. *See* column 6, lines 53-57 and Figure 12. Shikhman does not teach any devices or methods for securing body tissue.

### Meade

Meade discloses an endoscopic surgical tool having a tool actuating handle and a detachable tool assembly. *See* abstract and column 1, lines 55-56. The tool assembly comprises a tool having jaws pivotally mounted via a pivot pin to an extension. An outer sleeve is positioned about the extension and carries a drive pin which engages the tool. The handle retains

the extension in a fixed position but allows the tool to rotate and includes a trigger that can be moved to translate a sleeve back and forth over the extension. As the sleeve moves, the drive pin engages the tool to open and close the jaws. *See* abstract and column 1, lines 56-60. In one embodiment, illustrated in Figure 2c, the tool includes insulator cover 62 that covers sleeve 22. The insulator cover is preferably attached to the sleeve via a shrink fit. *See* column 5, lines 3-9 and Figure 2c. Meade's device is cost effective because the tool can be separated from its control mechanism and be replaced with a new one, thus replacement or maintenance of the entire device is not required. *See* column 1, lines 44-51 and column 2, lines 1-4.

#### Instant Invention

The instant invention provides a surgical device for securing tissue including an elongated insulation sleeve that is controllably positionable over the second member (force transmitting member and/or tubular member), *i.e.* the range of motion of the sleeve is limited and can be adjusted. This motion is not dependent on motion of the second member. *See* paragraph [0537] with Figures 52 and 53 of the published application.

#### Argument

Independent claims 1, 24, 25, 35, 43, 44, and 48 now recite that the elongated insulation sleeve of the surgical device is controllably positionable over the second/tubular member and movement of the sleeve is independent of the second/tubular member. Applicants respectfully disagree that the combination of teachings of Winston with either the teachings of Shikhman or the teachings of Meade discloses a surgical device including an elongated insulation sleeve that can be controllably positioned over a second member and wherein movement of the sleeve is independent of movement of this second member.

The Examiner states that the device of Winston has two compression elements **57a** and **46a**, as shown in Figure 3A, and that one is held rigidly to tube **70a** and the other is slidably movable inside the outer tube. The Examiner thus concludes that the device of Winston, as shown in Figure 3A, is the device of the instant invention with the exception of an insulation sleeve and a specific compressive force.

Applicants respectfully disagree. Element **57a** is an enlarged portion of tool member **55a** that is attached to insert **67a**. Support means **46a** is connected to leg **75a**. Neither element **57a** nor element **46a** is connected to the tubular housing, element **70a**. *See* column 10, lines 3-19, column 10, line 73 to column 11, line 1, and Figure 3A.

With regard to Shikhman, the Examiner states that this reference clearly discloses that the “obturator shaft **18** slides within cannula sleeve **28**” (column 4, lines 24-30) to either cover (Figure 2) or expose (Figure 1) the obturator tip **20**. Cannula sleeve **28** is rigidly attached to the cannula housing, however, the cannula sleeve and cannula housing can be moved in space as well as moved relative to the obturator. The Examiner thus concludes that the sleeve is capable of sliding independently relative to the obturator.

Applicants agree that the shaft slides within the sleeve, but disagree with regard to the independent movement of the sleeve. As discussed above, Shikhman discloses two types of sleeves, an obturator sleeve and a cannula sleeve, that are capable of functioning as insulation sleeves. However, neither sleeve is capable of independent movement as both are disclosed as rigidly connected to their respective housings. *See* column 4, lines 10-13, lines 24-26, and lines 41-44. The sleeve can not slide along any element and/or shaft of the device without coincident movement of the housing. Thus, as disclosed by Shikhman, the shaft moves within the sleeve, the sleeve does not move over the shaft. Furthermore, the movement of the shaft is mentioned only with regard to the interfitting of the cannula housing with the obturator housing to form the device. *See* column 4, lines 26-30 and Figure 1. Although the figures (Figures 2, 4, 6, 7, and 9) show the obturator tip as covered, the tip could not be covered in operation of the device since the tip functions to penetrate the tissue and contact of the tissue with the sleeve indicates that the tissue has been completely penetrated. Accordingly, the device disclosed by Shikhman would not function as indicated if the obturator tip remained covered by the sleeve in operation. Thus, a sleeve that is independently movable and controllably positionable is neither disclosed by nor relevant to the invention of Shikhman.

As noted in the previous Response and still considered as applicable herein, placing the entire device of Winston through the sleeve of Shikhman also does not teach the claimed invention. Merely surrounding the device of Winston with the sleeve of Shikhman does not

provide any means for connecting the sleeve to the device in a way that would allow the sleeve to be moved independently from the second member. The sleeve must be connected to the device somehow, and the teaching of Shikhman involves rigidly securing the sleeve to a sleeve housing. Furthermore, surrounding the device shown in Figure 3A of Winston with an insulation sleeve would have adverse consequences. For example, the energy source **71a** of Winston would be cut by the insulation sleeve. If a hole in the sleeve was provided for running the cable **72a** to the device, this would prevent the sleeve from being able to slide, notwithstanding the fact that Winston in view of Shikhman does not provide for a way of even sliding the insulation sleeve. Also, the second member in the device of Winston is moved towards the first member by providing a finger gripping means **77a**. Surrounding the entire device of Winston with an insulation sleeve would remove access to the finger gripping means and prevent the user from having the ability to move the first member towards the second member.

The prior art does not teach or suggest a device having an insulating sleeve that is controllably positionable and independently movable over the second member. Even if one of ordinary skill in the art were to combine the teachings of Winston and Shikman, one would not arrive at the surgical device as currently claimed, as Winston is silent regarding sleeves and Shikhman discloses only sleeves that are rigidly secured to other elements and thus, not independently movable. Furthermore, one would not have any reason or motivation to combine these teachings as the device of Winston and the device of Shikman are used for different purposes, Winston for securing tissue and Shikhman for penetrating tissue. One would not even consider these devices related or even associate them as useful together.

Independent claims 1, 24, 35, 44, and 48 now recite, *inter alia*, an elongated insulation sleeve controllably positionable over the second member, wherein movement of the sleeve is independent of movement of the second member.

Accordingly, Applicants respectfully submit that claims 1, 24, 35, 44, and 48 are patentable over Winston in view of Shikhman. As claims 2-5, 7, 8, 14-20, 22, 23, and 52 depend from claim 1, claim 53 depend from claim 24, claims 36-39, 42, 45, 46, and 55 depend from claim 35, claim 57 depends from claim 44, and claim 58 depends from claim 48, these dependent

claims necessarily include all the elements of their base claims. Thus, Applicants respectfully submit that the dependent claims are allowable over Winston in view of Shikhman for at least the same reasons.

Adding the teachings of Meade does not remedy the deficiencies of Winston with regard to independent claims 25 and 43. Claims 25 and 43 also include, *inter alia*, an elongated insulation sleeve controllably positionable over the second member, wherein movement of the sleeve is independent of movement of the second member.

Applicants note that the Examiner has not responded to arguments presented in the previous Response (filed on December 3, 2007) with regard to the combination of the teachings of Winston in view of Meade.

As discussed above, Meade discloses a surgical tool having an extension attached to a tool actuating handle. An outer sleeve is positioned about the extension and an insulator cover covers the sleeve. However, it is neither taught nor suggested that the insulator cover is controllably positionable over the outer sleeve or that it is capable of movement independent of the movement of the outer sleeve. In fact, in the preferred embodiment, the insulator cover is attached to the sleeve via a shrink fit. Thus, attaching the insulator cover to the sleeve would make the insulator cover incapable of moving from one position to another without moving the outer sleeve.

While Winston discloses a tubular member having a gapped portion, the reference does not disclose the tubular member having an insulator cover. Providing Winston with the insulator cover of Meade, however, would not provide for an insulator cover that is operative to be controllably moved from a first position, covering the gapped portion, to a second sleeve position, uncovering the gapped portion. As described above, Meade's insulator cover is not operative to move without movement of its outer sleeve because the reference neither teaches nor suggests having the insulator cover unattached to the outer sleeve. Thus, when providing Winston with the insulator cover of Meade, the insulator cover would move only when the tubular member moves. As such, the insulator cover would either have to be positioned to cover the gapped portion of the tubular member or positioned to uncover the gapped portion of the tubular member instead of being operative to cover and uncover the gapped portion by moving

the insulator cover without moving the tubular member. Therefore, this element of the claimed invention is not met by the disclosure of Meade.

The prior art does not teach or suggest a device having an insulating sleeve that is controllably positionable and independently movable over the second member. Even if one of ordinary skill in the art were to combine the teachings of Winston and Meade, one would not arrive at the surgical device as currently claimed, as Winston is silent regarding sleeves and Shikhman discloses only an insulator sleeve that is secured to another sleeve and thus, not independently movable.

Independent claims 25 and 43 now recite, *inter alia*, an elongated insulation sleeve controllably positionable over the second member, wherein movement of the sleeve is independent of movement of the second member.

Accordingly, Applicants respectfully submit that claims 25 and 43 are patentable over Winston in view of Meade. As claim 54 depends from claim 25 and claim 56 depends from claim 43, these dependent claims necessarily include all the elements of their base claims. Thus, Applicants respectfully submit that the dependent claims are allowable over Winston in view of Meade for at least the same reasons.

In light of all of the foregoing arguments, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-5, 7, 8, 10, 14-20, 22-25, 35-39, 42-46, and 48 under 35 U.S.C. §103(a).



### **Conclusion**

In light of the foregoing amendments and remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

The fee for a one month extension of time pursuant to Section 1.17(a)(1) in the amount of \$65 and the fee for extra claims pursuant to Section 1.16(i) in the amount of \$182 are believed to be due and are being paid via credit card. No other fees are believed to be due at this time. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-024).

Respectfully submitted,

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